February 29, 2000

Hon. Jane E. Henney, MD
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Final Rule on New Policies, Requirements and Procedures Pertaining to the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992. .64 Fed. Reg. 67,720 (December 3, 1999).

Dear Commissioner Henney:

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to advocate the views of small business before federal agencies and Congress. Advocacy is also required by section 612(a) of the Regulatory Flexibility Act (RFA)[1] to monitor agency compliance with the RFA. In addition, the Chief Counsel of Advocacy is authorized to appear as *amicus curiae* in regulatory appeals from final agency actions, and is allowed to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.[2] On March 28, 1996, President Clinton signed the Small Business Regulatory Enforcement Fairness Act (SBREFA)[3] which made a number of significant changes to the RFA, including the provision to allow judicial review of agencies' compliance with the RFA.[4]

These comments are intended to focus attention on the severe economic impact that will be placed on the drug wholesale industry as a result of the final rule referenced above. Based on this severe impact, and pursuant to the Administrative Procedure Act (APA), the Office of Advocacy hereby petitions the Food and Drug Administration (FDA) to reconsider this final rule, suspend the effective date, and reissue regulations that will effectuate the intent of Congress with respect to the Prescription Drug Marketing Act of 1987 (PDMA).[5]

Background

On March 14, 1994, FDA proposed regulations entitled, "Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992 (PD Amendments); Policies,

[1] 5 U.S.C. § 601 et seq.
[2] *Id.*
[3] Pub. L. No. 104-121, 110 Stat. 857 (1996).
[4] 5 U.SC. § 611.
[5] "Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

Requirements, and Administrative Procedures."[6] The proposed regulations were designed to implement the (then) seven-year-old PDMA and the PD Amendments. The primary intent of the PDMA was to combat abuses involved in the distribution of prescription drugs.[7] The PDMA contains drug pedigree requirements that impose prior sale documentation obligations on non-authorized distributors. Central to whether or not a business would have to comply with the documentation requirements was whether a business was "an authorized distributor of record" that maintained an "ongoing relationship" to distribute a manufacturer's products.

Subsequent to passage of the PDMA, FDA issued guidance on the meaning of "ongoing relationship" in the context of the manufacturer/wholesale distributor relationship.[8] Clearly, the 1988 guidance demonstrated that "ongoing relationship" was to be interpreted broadly so that "authorized distributors of record" may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's product. Among other criteria, the guidance indicated that the existence of two transactions in a two-year period would be presumptive evidence of a continuing relationship.

The PD Amendments of 1992 altered the pedigree requirements to increase the amount of information that had to be provided before each wholesale distribution of a drug. Under section 503(e) of the PDMA, the statement of prior sale now had to include the date of the transaction and the names and addresses of all parties to the transaction.

The most important thing to remember at this point is that Congress, in passing the PD Amendments, indicated no intent to alter either the definition of "authorized distributor of record" or FDA's guidance on the definition of "ongoing relationship."

The 1994 proposed regulations introduced a reversal of policy some six years after a standard for industry compliance had been established by FDA. For the first time, FDA would redefine "ongoing relationship" to mean:

> "An association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to sell the manufacturer's products for a period of time or for a number of shipments . . . and the name of the authorized distributor of record is entered on the manufacturer's list of authorized distributors of record." [9]

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[6] 42 Fed. Reg. 11,842.

[7] The PDMA requires the following: 1) state licensing of wholesale drug distributors; 2) a ban on the re-importation of prescription drugs produced in the U.S. (except when re-imported by the manufacturer or for emergencies; 3) a ban on the sale, trade or purchase of drug samples; 4) a ban on trafficking in or counterfeiting of drug coupons; 5) mandates on storage, handling and record keeping requirements for drug samples; 6) written practitioner requests for drug samples; 7) a prohibition on the resale of prescription drugs purchased by hospitals or other health care facilities; and, 8) criminal and civil penalties for violations.

[8] Food and Drug Administration, Compliance Policy Guide 7356.022 (August 1, 1988).

[9] 49 Fed. Reg. at 11,863.

Thus, FDA is now requiring a written statement between a manufacturer and each authorized distributor, and that distributors appear on the manufacturer's list of authorized distributors. This may seem like a fairly innocuous change on its face; but in reality, the changes make it much harder to become an authorized distributor and give manufacturers the sole discretion to determine whom to designate as an "authorized distributor."

FDA's new scheme ignores the reality of the drug distribution chain that exist now under the statute. Secondary wholesale distributors will have to provide information about "each prior sale, purchase or trade of such drug . . ., starting with the manufacturer."[10] This means that secondary distributors must provide a full pedigree even if that distributor purchased the drug from an authorized distributor, and even though the authorized distributor is under no legal to obligation to provide a pedigree to secondary distributors. How is the secondary distributor to get the pedigree?

The industry raised these serious concerns described above in their 1994 comments to FDA.[11] The industry suggested, alternatively, that FDA revise the proposal to require that the pedigree only go back to the last authorized distributor of record—a seemingly reasonable solution. This recommendation was rejected and FDA has chosen to move forward with the final regulation without substantial change.

The Final Rule and Its Impact on Small Business

By FDA's own account, at least 4,000 small businesses (94% of the industry) will be affected by this rulemaking.[12] FDA, however, concluded that the impact would not be significant. In dismissing the industry's arguments to the contrary, FDA stated,

> "Section 503(e)(1)(A) of the act [PDMA] requires that, prior to completion of a wholesale distribution of a prescription drug by a person who is not the manufacturer or an authorized distributor of the drug, a statement must be provided to the recipient identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction. There is no indication in PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor. Thus, an unauthorized distributor is required to provide a full drug origin statement in accordance with PDMA and the final rule whether or not it has purchased a prescription drug from an authorized distributor of record. Although the agency encourages authorized distributors to provide a drug origin statement to unauthorized distributors, they are not required to do so under PDMA or the final rule."

[10] 64 Fed. Reg. at 67,747.
[11] *See* Letter from the American Association of Pharmaceutical Distributors to the Food and Drug Administration (May 31, 1994).
[12] 64 Fed. Reg. at 67,753.

FDA apparently has not considered the possibility that Congress did not specifically prohibit the interpretation proposed by the industry. Nor has FDA taken into consideration the impact of abandoning its long standing guidance. In any event, FDA certainly has not provided a rational explanation for its reversal.

With regard to the written agreement whereby the manufacturer authorizes the distributor to distribute some or all of its products, FDA simply stated,

> "Given the relative ease with which the agreement required by § 203.3(u) can be created, the agency believes that it is highly unlikely that a manufacturer would refuse to enter into a written agreement with a distributor with whom it whishes to have a continuing business relationship. Moreover, it is clearly not the agency's intent in requiring a written agreement to confer additional discretion on manufacturers, but rather to implement the requirement in the act for an ongoing relationship in a manner in which it can be efficiently enforced." [13]

Again, this response ignores the reality of the relationship between secondary drug wholesalers and manufacturers. The drug wholesalers are entirely at the mercy of manufacturers. The fact that an agreement is easily created is irrelevant if the manufacturer chooses to limit whom it considers authorized dealers. Moreover, the fact that FDA does not intend to confer additional discretion on manufacturers, does nothing to change the fact that the door is open for manufacturers to "cherry pick" and create a situation where secondary marketers are eliminated and consumer prices more easily increased.

FDA's responses to the industry are unacceptable. The final rule was modified to remove the requirement for a completed sale under the written agreement; however, FDA's responses largely ignore obvious impacts on the industry. First, according to industry experts, authorized wholesalers (even large ones) are not now able to and could not, at any reasonable cost, provide pedigrees to those to whom they distribute drugs. Moreover, because they are authorized distributors of record, they are not required to do so. Second, wholesalers buying from full line wholesalers that do not provide a pedigree will not be able to pass along to their customers a pedigree describing transactional information back to the manufacturer. And, third, full line wholesalers who now buy from the secondary market will not be able to do so because the secondary market will not be able to provide them with pedigrees back to the manufacturer.

All of the above will be exacerbated by FDA's final regulation requirement that there be a writing from the manufacturer to the distributor indicating that it is an authorized distributor. In the past, FDA accepted two transactions in two years between a wholesaler and a manufacturer as evidence that a distributor is authorized. Now, such transactions will not be sufficient. This will further restrict the secondary market. Even as the market stands now, some manufacturers refuse to do business with wholesaler to prevent them from claiming "authorized" status.

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[13] 64 Fed. Reg. at 67,728.

In the end, serious disruption can be expected in the prescription drug distribution system—resulting in less competition, higher prices and lost jobs.

Unanticipated Impact

Not even the industry anticipated all of the adverse impacts that would be associated with implementation of this regulation. Drug products now in the inventory of wholesalers will have to be cleared out and new orders will have to cease or be severely limited in order to comply with the December 4, 2000 effective date. Unless distributors have relief by this summer, disruptions could begin to appear then. The Office of Advocacy has a letter from one Texas manufacturer that underscores this possibility, "we are modifying our procedures for reviewing pedigrees to ensure we are closer to following the new regulations which take effect on December 4th, 2000. Beginning on March 1st, 2000 all invoices received without a complete pedigree will not be paid." The problem, therefore, needs to be addressed immediately.

Conclusion

Again, the Office of Advocacy petitions FDA to reconsider its decisions underlying this regulation and to suspend implementation immediately until the impacts are more carefully studied and understood by FDA, and adjustments are made to avoid adverse disruptions. FDA should reissue the regulation after a more thorough review of impacts. Advocacy believes that this approach is consistent with congressional intent and is consistent with the agency's objective to ensure that suspect products do not enter the distribution system. Please do not hesitate to contact my office if you have any questions, 202-205-6533.

Sincerely,

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